

### **REMARKS**

The above Amendments and these Remarks are submitted under 35 U.S.C. § 132 and 37 C.F.R. § 1.111 in response to the Office Action mailed August 16, 2004.

#### **Summary of the Examiner's Action and Applicants' Response**

The Examiner stated that Claims 1-27, 36, and 37 have been allowed. The Examiner stated that Claims 31 and 32 would be allowable if converted to independent form. Claims 28-30, 33, 34, and 35 were rejected by the Examiner under 35 U.S.C. §102 as being anticipated by Jassawalla, et al., U.S. Patent No. 6,264,601. The Examiner has rejected Claims 38-40 under 35 U.S.C. §102 as being anticipated by Kolff, U.S. Patent No. 4,427,470. In response, Claims 28, 31, 33, and 34 have been amended. Claim 30 has been canceled. Applicants have amended the specification to correct minor typographical errors regarding certain equations. Claims 1-29 and 31-40 remain pending.

#### **Response to Objection to Claims 31 and 32**

The Examiner stated that Claims 31 and 32 would be allowable if converted to independent form. In response, Claim 31 has been converted into independent and thus allowable form. Claim 32 depends from Claim 31 and is respectfully submitted as also being in allowable form. Applicants respectfully request therefore, that the objection to Claims 31 and 32 be withdrawn.

#### **Response to Rejection of Claims 28-30, 33, 34, and 35 under 35 U.S.C. §102(b)**

The Examiner rejected Claims 28-30, 33, 34, and 35 under 35 U.S.C. §102 as being anticipated by Jassawalla, et al. In response, Applicants have amended Claim 28 to further differentiate Jassawalla, et al. The device in Claim 28, as amended, includes a sensor that detects a **negative** pressure within the first chamber and a controller triggered by an output of the sensor for actuating a blood pump. The sensor responds only to the negative pressure within the first chamber. Support for this amendment is found in the specification in paragraphs [00150] and [00151]. In contrast, Jassawalla, et al. discloses a sensor 130 for measuring ventricular pressure, which is always positive. Jassawalla, et al. does not disclose a sensor for detecting negative pressure or actuating a pump based on the output of such a sensor.

For the above reasons, Applicant respectfully submits that Jassawalla, et al. does not anticipate Claim 28. Claim 29 depends from Claim 28 and is respectfully submitted as not being anticipated by Jassawalla, et al. for the same reasons as for Claim 28.

Claim 33 has been amended so that it depends from Claim 31. As stated above, Claim 31 has been amended into allowable form. Applicants respectfully submit therefore that Claim 33 is allowable for the above reasons for Claim 31.

Claim 34 has been amended to further differentiate Jassawalla, et al. The method in Claim 34, as amended, includes initiating a ventricular assist device as a function of a sensor that detects a negative pressure in the device. As discussed above with respect to Claim 28, Jassawalla, et al. does not disclose a sensor that detects negative pressure. Jassawalla, et al. also does not disclose use of a negative pressure sensor for initiating a ventricular assist device. For the above reasons, Applicant respectfully submits that Jassawalla, et al. does not anticipate Claim 34.

Regarding Claim 35, the Examiner stated in his rejection of Claim 35 that Jassawalla, et al. discloses a ventricular pressure sensor 130. Applicants respectfully disagree. Claim 35 does not, in fact, include a sensor. Claim 35 is directed to a method of controlling a ventricular assist device having at least one valve and an electromagnetically driven pump comprising driving said pump to minimize the force on at least one of said at least one valve. Applicants respectfully submit that Jassawalla, et al. does not disclose driving an electromagnetic pump to minimize the force on at least one of the at least one valve, as claimed in Claim 35. For the above reasons, Applicants respectfully submit that Jassawalla, et al. does not anticipate Claim 35.

**Response to Rejection of Claims 38-40 under 35 U.S.C. §102(b)**

The Examiner rejected Claims 38-40 under 35 U.S.C. §102 as being anticipated by Kolff. The Examiner states that Kolff discloses a first one-way valve comprising valve 36 and a second one-way valve comprising 66, 68, and 70. The Examiner concludes that Claim 38 is anticipated by Kolff. Applicants respectfully disagree. Applicants respectfully submit that Kolff does not disclose a device with two chambers and a one-way valve such that the first chamber simultaneously increases in volume as the second chamber decreases in volume with said one-way valve closed during a pump stroke, as claimed in Claim 38. Kolff discloses a device where the first chamber can increase or decrease in volume independently of the actuation of the second chamber. (See FIGs. 5B and 6B and Col. 6, line 12-9-54). Consequently, Kolff discloses a different mechanism by which the interconnecting valve closes. According to the present invention, the valve is subjected to the simultaneous decrease in pressure in the first chamber and increase in pressure in the second chamber, as claimed in Claim 38. In contrast, the device disclosed in Kolff experiences only the latter, i.e., an increase in pressure in the second chamber.

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Kolff also does not disclose the method claimed in Claim 38 regarding the opening of the valve. For the present invention, as claimed in Claim 38, the valve opens in response to the increase in pressure in the first chamber as well as the simultaneous decrease in pressure in the second chamber. In contrast, the method disclosed in Kolff has only the latter, i.e., a decrease in pressure in the second chamber. Moreover, as claimed in Claim 38, by rapidly terminating the pump stroke, the momentum of the blood causes the valve to open. This step represents a second opening of the valve, in addition to the normal opening that occurs when the second chamber fills. Kolff does not disclose this "rapidly terminating" step.

Based on the above, Applicants respectfully submit that Claim 38 is not anticipated by Kolff. Claims 39 and 40 depend from Claim 38 and are respectfully submitted as not being anticipated by Kolff for the same reasons above for Claim 38.


Regarding Claim 40, Kolff also does not disclose the active filling capability of the pump, as claimed in Claim 40. The active filling capability of the pump derives from the simultaneous increase in volume of the first (filling) chamber with the decrease in volume of the second chamber, i.e., as blood is actively expelled through the device outlet, it is simultaneously drawn in through the device inlet. This active filling can not occur with the Kolff device, wherein the first chamber fills passively. Applicants respectfully submit that, for this additional reason as well, Claim 40 is not anticipated by Kolff.

### Conclusion

For the above reasons, Applicants respectfully submit that all pending claims, Claims 1-29 and 31-40, in the present application are in condition for allowance. Such allowance is respectfully solicited. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 739-2800.

Respectfully submitted,

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